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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/412,539 | 10/04/1999 | LOUIS S. KUCERA | 0044317U3 | 9782 |

28977 7590 12/24/2003
MORGAN, LEWIS & BOCKIUS LLP
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PHILADELPHIA, PA 19103-2921

EXAMINER

COLEMAN, BRENDA LIBBY

| | |
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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/412,539

Applicant(s)
KUCERA et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 17, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56, 69-71, 107, and 110-112 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56, 69-71, 107, and 110-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 56, 69-71, 107 and 110-112 are pending in the application.

This action is in response to applicants' amendment and RCE filed October 17, 2003.

Claims 56 and 107 have been amended.

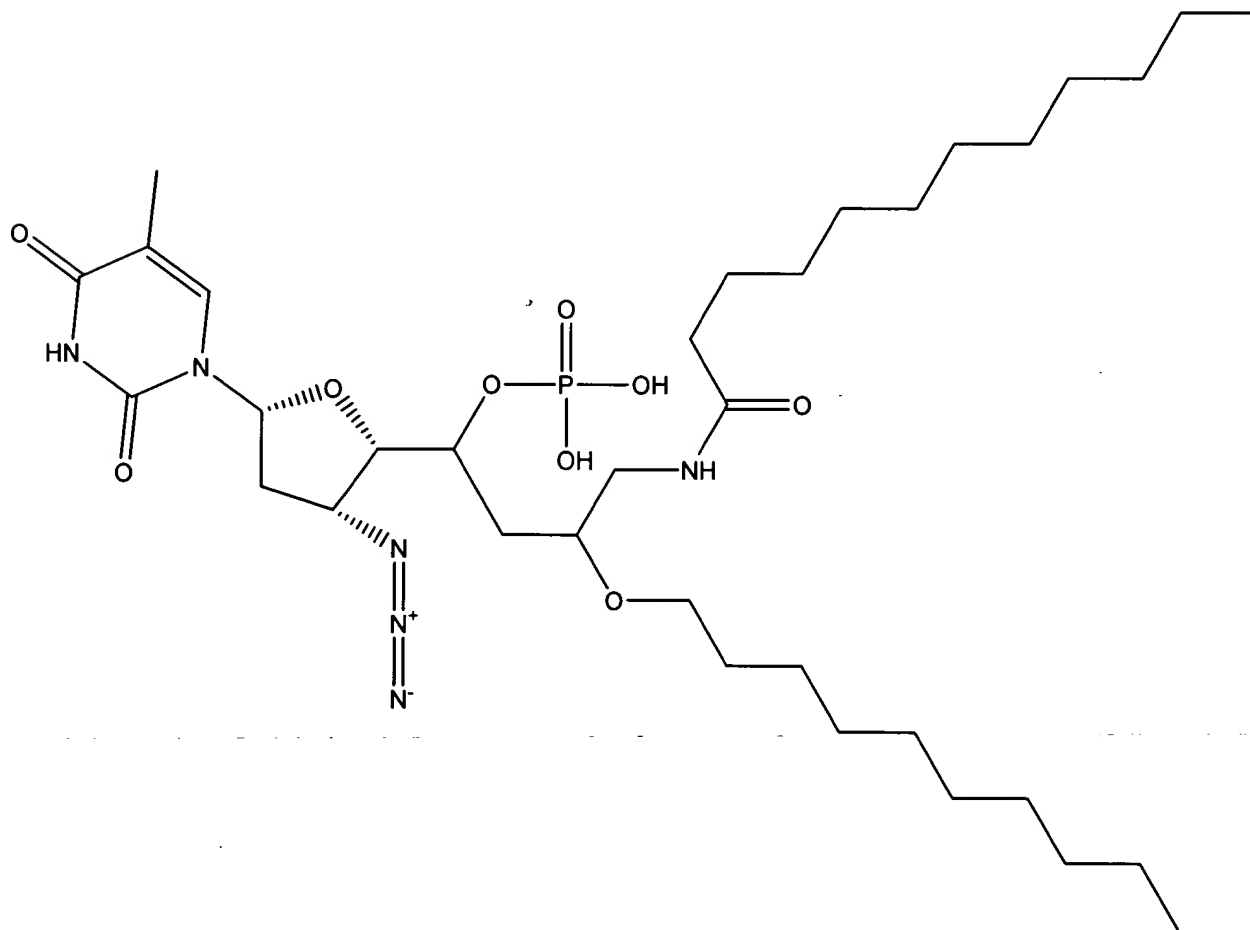
Response to Amendment

Applicant's amendment October 17, 2003 has been fully considered with the following effect:

1. The applicants' arguments are sufficient to overcome the objection to the specification under 35 U.S.C. 132 maintained in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the objection to the 35 USC § 112, first paragraph rejection of claims 56, 69-71, 107 and 110-112 labeled paragraph 2 of the last office action, which is hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 101 rejection of claims 56, 69-71, 95, 107 and 109-112 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants stated that "the specification recites as an exemplary preferred compound of Formula III, 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine". However, 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine is not a compound of Formula III. The nomenclature of examples 5 and 6 do not coincide with the structure of Formula III. The nomenclature of examples 5 and 6 are such

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that the (3-dodecanamido-2-decyloxypropyl) and (3-dodecyloxy-2-decyloxypropyl) portion of the compound is bound to the 5' position, which indicates that the (3-dodecanamido-2-decyloxypropyl) and (3-dodecyloxy-2-decyloxypropyl) is bound to the furan at the carbon atom next to the O atom. This is not consistent with the structure of amended Formula III.



Additionally, the structure of 3'-azido-3'-deoxy-

5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine as drawn by ChemDraw is as shown above. The inconsistency of the nomenclature and the structure of Formula III does not provide

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enablement for the compounds of examples 5 and 6 which are not of Formula III and hence possess no statement of utility.

The applicants also stated that "Examples 5 and 6 found on pages 21-23 of the specification illustrate how to make 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine and 3'-azido-3'-deoxy-5'-(3-dodecyloxy-2-decyloxypropyl)-phosphothymidine". However, "how to make" does not satisfy the "how to use" prong of utility for the compounds.

Claims 56, 69-71, 107 and 110-112 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. For reasons of record and stated above.

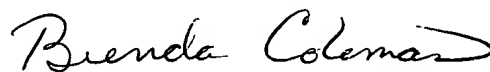
Claims 56, 69-71, 107 and 110-112 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

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The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
December 15, 2003